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RE: Formulation with preservatives; follow up

Dear Folks:

This proposal responds to the Agency's letter dated October 18, 2018 discussing the use of alternative BIT sources in pesticide formulations. That letter describes a "Batched Notification Process with Self Certification" (attachment Part A point 1); "Changes in source of BIT as an inert ingredient" (attachment Part A point 2); and "Use of Streamlined Minor Formulation Amendment Process with Self Certification – Changes from BIT to BIT/MIT/" (attachment Part B).

The expedited work of the Agency is greatly appreciated and is useful for producers who are able to acquire the described alternate sources of BIT. However, due to the worldwide shortage of BIT and despite the approval of these alternate sources, other solutions need to be considered to ensure that the range of FIFRA-registered products is available to users, and have acceptable shelf life.

The October 18 letter requests "specific proposals from industry to address disruptions in the availability of BIT which address options such as the use of BIT-free formulations and use of

other, non-BIT preservatives (e.g., substitution of BIT with a CIT/MIT-only product)." We offer the following expanded proposal:

1. Expand the process for "Batched Notification with Self-Certification" to cover use of registered formulations of single and multiple active ingredients, referenced in the tables below, indicating the acceptable use(s) of each.
2. Affirm the understanding that maximum concentrations approved in pesticide formulations, appearing on the most recent EPA-approved labels, will be observed.
3. Any specific concentration limits for preservative ingredients in pesticide formulations registered for food-crop use that are expressed in the relevant tolerance exemptions (40 CFR §§180.910, 920, & 950) will be observed. Lower use levels than those of the formerly used BIT-based biocides will be allowed.
4. The quantity of a BIT replacement used may or may not correspond exactly to the BIT-based biocide that it replaces, owing to differences in potency, active ingredient concentration, and approved label use rates, but it will be similarly low
5. **Tables A through E are listed in priority order. If some tables can be approved before others, we request that the approvals be communicated promptly, so that registrants can proceed with production for the coming growing season.**
    a. Table A: Registered formulations basing on CIT/MIT (independently of the ratio of CIT/MIT) and bronopol.
    b. Table B: Registered formulations basing on bronopol alone.
    c. Table C: Registered formulations basing on the *cis*-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane, also commonly known as adamantane or CTAC; sodium 2-phenylphenate (NaOPP); and 3-iodo-2-propynyl butyl carbamate (IPBC).
    d. Table D: Additional registered food- and Non-food only formulations.
    e. Table E: Additional chemicals, not subject to FIFRA registration but regulated as inert ingredients. Most of the chemicals listed have tolerance exemptions, as shown. A few do not, but can be used in formulating products for non-food-crop uses.
6. The "Batched Notification with Self-Certification" process would also cover the following situations:
    a. Any registered microbiocide product bearing an EPA registration number from tables A through D is acceptable for use, though it may bear an alternate trade name, alternate container label, or a distributor label.
    b. If the BIT product listed on a product's CSF is unavailable, the BIT may be omitted from the formulation entirely, without the replacement by other preservatives, at the discretion of the registrant. In such a situation, the Quantity Sufficient (QS), otherwise known as filler (generally water), will be adjusted as needed. This might occur where –
        i. The pesticide formulation already has other preservative ingredients that can provide sufficient protection; or
        ii. A batch of formulated pesticide product will be sold and used promptly after manufacture, not needing the preservative protection during a short shelf life.

c. Additional minor formulation adjustments needed to insure stability, such as addition of acid(s), base(s), or buffer(s) to adjust pH, are acceptable. Such minor additives, ordinarily used at levels of a fraction of a percent of the formulation, must be approved inerts and have tolerance exemptions, if applicable. Such changes would be expected to have no adverse impact on the safety of the products.

7. Preservative products and ingredients that have tolerance exemptions can also be used to formulate pesticide products for non-food-crop uses.
8. Registrants using the batched self-certification process should not submit amended CSFs for the affected products during the interim 2-year period, unless and until the formulation changes are intended to become permanent. No further action by the registrant is necessary regarding BIT replacement if the BIT shortage is resolved within that 2-year period and the product formulation reverts to a CSF already on file with the Agency.

We believe that these points are consistent with the streamlined self-certification process described in the Agency's October 18 letter. Further, we believe that the non-BIT preservatives listed in the tables attached to this letter meet the criteria used to satisfy PR Notice 98-10, Section V.A.3. With diminishing BIT inventory, these are the only known alternative products available and widely accepted by the industry as being efficacious when used properly.

This action is necessary to avoid undue burden on the Agency's resources. Without it, registrants could soon be forced to prioritize which products can and cannot be produced, until the BIT supply is restored.

We appreciate the Agency's efforts to approve this specific request for non-BIT preservatives in an expedited manner as a corollary of the Agency's previous response that provided a streamlined process for the substitution of by other chemistries. Anecdotal reports indicate some companies are running out of BIT product in November. The above request is vital for production of crop protection chemicals for the upcoming growing season.

Sincerely,

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PRODUCT TABLES

A. Registered CIT/MIT products, including CIT/MIT/Bronopol combinations.					
EPA Reg. No.	**Product Name(s)**	**Company Name**	**Active ingredient(s)**	**Percent Active Ingredient**	**Tolerance Exemption**
39967-79	PREVENTOL P 91	LANXESS CORPORATION	CIT/MIT (3:1)	1.1	920
			Bronopol	9.97	
39967-93	PREVENTOL D 7 CF	LANXESS CORPORATION	CIT/MIT (3:1)	1.5	920
67071-1	ACTICIDE LG ACTICIDE CT ACTICIDE MV	THOR GMBH	CIT/MIT (3:1)	1.48	920
67071-5	ACTICIDE 14	THOR GMBH	CIT/MIT (3:1)	14.1	920
67071-50	ACTICIDE 2605	THOR GMBH	CIT/MIT (3:1)	2.6	non-food only
			Bronopol	5.3	
67071-10	ACTICIDE RS	THOR GMBH	CIT/MIT (3:1)	1.48	920
67071-11	ACTICIDE SPX	THOR GMBH	CIT/MIT (3:1)	1.48	920
67071-16	ACTICIDE LA ACTICIDE LA 1209	THOR GMBH	CIT/MIT (3:1)	1.13	920
			Bronopol	8.8	
67071-18	ACTICIDE SR 2060 ACTICIDE GA ACTICIDE LA 1206	THOR GMBH	CIT/MIT (3:1)	1.13	920
			Bronopol	5.2	
67071-91	ACTICIDE LA 1016	THOR GMBH	CIT/MIT (3:1)	0.96	920
			Bronopol	16.36	
6836-241	ISOCIL IG	LONZA INC	CIT/MIT (3:1)	1.58	920
707-166	KATHON CG-ICP	DOW CHEMICAL COMPANY	CIT/MIT (3:1)	1.5	920
707-196	KATHON CG-ICP II	DOW CHEMICAL COMPANY	CIT/MIT (3:1)	1.5	920
82760-2	BCS 3024CF	BULK CHEMICAL SERVICES	CIT/MIT (3:1)	1.5	920
6836-259	ISOCIL IG-C CMC- E	LONZA INC	CIT/MIT (3:1)	1.5	non-food only
1258-1339	PROXEL CMC	ARCH CHEMICALS INC	CIT/MIT (3:1)	1.5	non-food only
5383-103	MERGAL CM1.5	TROY CHEMICAL CORPORATION	CIT/MIT (3:1)	1.5	non-food only
5383-141	MERGAL MC14	TROY CHEMICAL CORPORATION	CIT/MIT (3:1)	14.6	non-food only

B. Registered Bronopol only products.

EPA Reg. No.	Product Name(s)	Company Name	Active ingredient(s)	Percent Active Ingredient	Tolerance Exemption
33753-20	MYACIDE S30	BASF CORPORATION	Bronopol	30.0	910
464-685	BIOBAN BP-30 PRESERVATIVE	DOW CHEMICAL COMPANY	Bronopol	30.0	910
67071-75	ACTICIDE L 30	THOR GMBH	Bronopol	30.0	910
39967-64	PREVENTOL P 30	LANXESS CORPORATION	Bronopol	30.0	910
39967-130	PREVENTOL P 30 S	LANXESS CORPORATION	Bronopol	30.0	910

C. Registered cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (CTAC); sodium 2-phenylphenate (NaOPP); and 3-Iodo-2-Propynyl Butyl Carbamate (IPBC)

EPA Reg. No.	Product Name	Company Name	Active ingredient(s)	Percent Active Ingredient	Tolerance Exemption
464-327	DOWICIL 150 ANTIMICROBIAL	DOW CHEMICAL COMPANY	CTAC	96	920
464-78	DOWICIDE A ANTIMICROBIAL	DOW CHEMICAL COMPANY	NAOPP	71.7	920
5383-55	POLYPHASE EC17	TROY CHEMICAL CORPORATION	IPBC	17	non-food only
5383-118	POLYPHASE LA33	TROY CHEMICAL CORPORATION	IPBC	17	non-food only

D. Registered MIT, MIT/BIT, MIT/BIT/Bronopol products, BIT/Bronopol, MIT/CIT/BIT

EPA Reg. No.	Product Name	Company Name	Active ingredient(s)	Percent Active Ingredient	Tolerance Exemption
39967-153 *	PREVENTOL BM5	LANXESS CORPORATION	MIT	2.5	non-food only
			BIT	2.5	
67071-29 *	ACTICIDE MBS	THOR GMBH	MIT	2.5	non-food only
			BIT	2.5	
67071-56 *	ACTICIDE MBS 2550	THOR GMBH	MIT	2.5	non-food only
			BIT	5.0	
67071-62 *	ACTICIDE CBM 2	THOR GMBH	MIT/CIT	6	non-food only
			BIT	10	
67071-26	ACTICIDE M20 S	THOR GMBH	MIT	20	non-food only
67071-46 *	ACTICIDE MBL	THOR GMBH	MIT	2.5	non-food only
			BIT	2.5	
			Bronopol	8.0	
1258-1290 *	PROXEL BN PRESERVATIVE	ARCH CHEMICALS INC	BIT	13.5	920
			Bronopol	6.5	

* Still subject to BIT shortage.

E. Preservatives not subject to FIFRA pesticide registration but regulated as inert ingredients	
Substance	**Tolerance Exemption**
ammonium persulfate	910
ascorbyl palmitate	910
benzoic acid	910
benzoic acid, potassium salt	910
benzoic acid, sodium salt	950e
methyl paraben	920
methyl paraben, sodium salt	non-food only
propyl paraben	910
propyl paraben, sodium salt	non-food only
sorbic acid	910
sorbic acid, potassium salt	950e